510(k) Summary

Disc-O-Tech Medical Technologies, Ltd.
Fixion® Interlocking Proximal Femoral Intramedullary Nailing System; Fixion® Intramedullary Nailing System; Fixion® Interlocking Intramedullary Nailing System; Fixion™ Unipolar Modular Hemi-Hip System

Company Name
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St., Herzliya
Israel, 46728

Submitter's Name and Contact Person
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Date Prepared
October 2002

Trade/Proprietary Name
Fixion® Interlocking Proximal Femoral Intramedullary Nailing System; Fixion® Intramedullary Nailing System; Fixion® Interlocking Intramedullary Nailing System; Fixion™ Unipolar Modular Hemi-Hip System

Classification Name
21 CFR § 888.3020, Class II, Intramedullary fixation rod
21 CFR § 888.3390, Class II, Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis

Predicate Devices
1. Fixion Interlocking Proximal Femoral Intramedullary Nailing System (K010988, K012967) by Disc-O-Tech Medical Technologies, Ltd.

Performance Standards
The following standards were used:
1. The Fixion PF Nail is manufactured from 316L Stainless Steel, which meets the requirements of ASTM F 138 Standard Specification for Stainless Steel Bar and Wire for Surgical Implants.
2. The Fixion PF Nailing System accessories incorporate surgical grade Stainless Steel, Silicone

and Celeron.

3. The Fixion PF Nailing System is designed to meet the requirements of ASTM F 565 Standard Practice for Care and Handling of Orthopedic Implants and Instruments.

Intended Use

Hip:

- femoral head/neck fractures or non-unions;
- aseptic necrosis of the femoral head/neck; and
- osteo-, rheumatoid, and post-traumatic arthritis of the hip, with minimal acetabular involvement

Femur:

- fractures in the femur shaft, proximal femoral fractures, and combinations of these fractures; proximal femoral fractures including stable and unstable pertrochanteric, intertrochanteric, and subtrochanteric (with and without break-off of the minor trochanter), high subtrochanteric fractures and combinations of these fractures;
- use in osteotomy, nonunions and malunions, bone reconstruction following tumor resection, grafting and pathological fractures, and revision procedures in the femur;
- mid shaft fractures in the femur (5 cm below the surgical neck to 5 cm proximal to the distal end of the medullar canal);
- comminuted shaft fractures;
- fixation of short distal or proximal fragments

Tibia:

- diaphyseal shaft fractures in the tibia;
- comminuted shaft fractures;
- fixation of short distal or proximal fragments

Humerus:

- diaphyseal shaft fractures in the humerus;
- comminuted shaft fractures;
- fixation of short distal or proximal fragments

Substantial Equivalence

The Inflation Device (Nail Pump/Hip Peg Pump), which incorporates new materials and a slightly revised design, is still intended to operate in a manner similar to the Pump currently used with the aforementioned Fixion Systems and all materials incorporated into it are already used in instrumentation supplied with those systems.

The Fixion Interlocking Proximal Femoral Intramedullary Nailing System is substantially equivalent to the following cleared Fixion Systems: Fixion IM Nailing System – K990717, K003212, K003215, K010901, K021324; Fixion IL Nailing System – K002783, K013449; and Fixion UH Hemi-Hip System – K014072. The modified Fixion PF Nailing System (modified

Pump) has the following similarities to that which previously received 510(k) clearance:

- Have the same intended use
- Have the same operating principles
- The Implants and the Instrumentation Set incorporate the same design
- The Implants and the Instrumentation Set incorporate the same materials
- The Implants and the Instrumentation Set have the same basic packaging and sterilization, using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2002

Ms. Yael Rubin
Director of Regulatory Affairs
Disc-o-Tech Medical Technologies, Ltd.
3 Hasadnaot St.
Herzliya 46728
ISRAEL

Re: K023437
Trade/Device Name: Fixion™ Interlocking Proximal Femoral Intramedullary Nailing System; Fixion™ Intramedullary Nailing System; Fixion™ Interlocking Intramedullary Nailing System; Fixion™ Unipolar Modular Hemi-Hip System
Regulation Number: 21 CFR 888.3020; 21 CFR 888.3390
Regulation Name: Intramedullary fixation rod; Hip joint (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: HSB, JDS, KWY
Dated: October 10, 2002
Received: October 15, 2002

Dear Ms. Rubin:

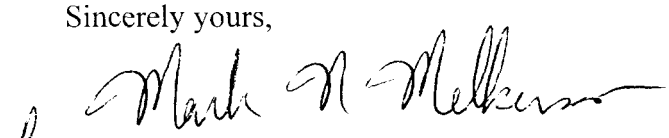
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosures) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K023437

Device Name: Fixion® Interlocking Proximal Femoral Intramedullary Nailing System; Fixion® Intramedullary Nailing System; Fixion® Interlocking Intramedullary Nailing System; Fixion™ Unipolar Modular Hemi-Hip System

Indications For Use: These devices are indicated for the following:

Hip:
- femoral head/neck fractures or non-unions;
- aseptic necrosis of the femoral head/neck; and
- osteo-, rheumatoid, and post-traumatic arthritis of the hip, with minimal acetabular involvement

Femur:
- fractures in the femur shaft, proximal femoral fractures, and combinations of these fractures; proximal femoral fractures including stable and unstable pertrochanteric, intertrochanteric, and subtrochanteric (with and without break-off of the minor trochanter), high subtrochanteric fractures and combinations of these fractures;
- use in osteotomy, nonunions and malunions, bone reconstruction following tumor resection, grafting and pathological fractures, and revision procedures in the femur;
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- fixation of short distal or proximal fragments

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- comminuted shaft fractures;
- fixation of short distal or proximal fragments

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR § 801.109)

OR

Over-the-Counter Use _____ (Optional Format 1-2-96)

for Mark N Milham

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023437